



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GDM/JR-M020103-WO		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/GB 03/03393		International filing date (day/month/year) 04.08.2003	Priority date (day/month/year) 02.08.2002
International Patent Classification (IPC) or both national classification and IPC A61L31/14			
Applicant RALINEA LIMITED			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 28.01.2004		Date of completion of this report 08.11.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Heck, G Telephone No. +31 70 340-3288 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/03393**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-24, 26-28	as originally filed
25	received on 30.10.2003 with letter of 30.10.2003

Claims, Numbers

1-12	as originally filed
------	---------------------

Drawings, Sheets

1/15-15/15	received on 30.09.2003 with letter of 30.09.2003
------------	--

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/03393**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12

because:

☒ the said international application, or the said claims Nos. 12 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-11
	No: Claims	-
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-11
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	-

2. Citations and explanations

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/03393**

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/03393

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Since claim 12 is directed to a method of treatment of the human or animal body by surgery, it relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. For the assessment of the subject-matter of present claim 12 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. Therefore, no opinion will be formulated with respect to the subject-matter of claim 12 (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document (D1) cited in the International search report:

D1 ... US 5,108,413 A (Moyers R.E.)

Document D1 discloses (cf. claims 1, 2, 10, 11) a dilator for opening the lumen of a tubular organ comprising an elongated flexible expansion member of a material having a negative Poisson ratio. The subject-matter of claims 1-11 of the present application differs from the disclosure of D1 in that both ends of the tubular liner are open and is therefore novel according to Article 33(2) PCT.

Document D1, which is considered the most relevant state of the art, discloses (cf. col. 1, lines 43-45 ; claims 1, 2, 10, 11) a dilator for opening the lumen of a tubular body organ comprising an elongated flexible expansion member of a material having a negative Poisson ratio to obtain a known and controllable radial expansion.

In view of D1, the objective technical problem underlying the present application is considered to provide devices for lining *in vivo* ducts which allow for a known and controllable radial expansion.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/03393

The solution is a tubular liner for insertion into an *in vivo* duct with two open ends to allow for fluid flow through the liner comprising an auxetic material.

The subject-matter of claims 1-11 of the present application is not limited to implantable or biocompatible liners. According to the Applicant, there is no reason why the teaching of this document should be limited to *in vivo* ducts.

According to the preliminary examination authority, the limitation to *in vivo* ducts is essential. The application does not contain any mention of other types of ducts and it is not apparent how the application of the tubular liner to other types of ducts would be useful.

Therefore, the objective technical problem has been defined above as to provide devices for lining *in vivo* ducts so that the technical problem is not solved over the whole scope of the claims.

Since this objective technical problem is not solved over the whole scope of the claims, the subject-matter of claims 1-11 cannot be considered to involve an inventive activity according to Article 33(3) PCT.

The subject-matter of claims 1-11 of the present application fulfils the requirements of Article 33(4) PCT concerning the industrial applicability.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Lloyd Wise, McNeight & Lawrence
Highbank House
Exchange street
Stockport, Cheshire SK3 0ET
GRANDE BRETAGNE

PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing (day/month/year)		26.04.2004
Applicant's or agent's file reference GDM/JR-M020103-WO		REPLY DUE within 3 month(s) from the above date of mailing
International application No. PCT/GB 03/03393	International filing date (day/month/year) 04.08.2003	Priority date (day/month/year) 02.08.2002
International Patent Classification (IPC) or both national classification and IPC A61L31/14		
Applicant RALINEA LIMITED		

- This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
 - ☒ Basis of the opinion
 - ☐ Priority
 - ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Lack of unity of invention
 - ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Certain documents cited
 - ☐ Certain defects in the international application
 - ☐ Certain observations on the international application
- The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 02.12.2004

Name and mailing address of the International preliminary examining authority:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 851 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Heck, G

Formalities officer (Incl. extension of time limits)

Janzing, M

Telephone No. +31 70 340-1140



WRITTEN OPINION

International application No.

PCT/GB 03/03393**I. Basis of the opinion**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-24, 26-28

as originally filed

25

received on 30.10.2003 with letter of 30.10.2003

Claims, Numbers

1-12

as originally filed

Drawings, Sheets

1/15-15/15

received on 30.09.2003 with letter of 30.09.2003

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
 - ☐ the claims, Nos.:
 - ☐ the drawings, sheets:
5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
6. Additional observations, if necessary:

WRITTEN OPINIONInternational application No. **PCT/GB 03/03393****III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve a inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 12

because:

☒ the said international application, or the said claims Nos. 12 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1 (no), 2-11 (yes)
Inventive step (IS)	Claims	1-11 (no)
Industrial applicability (IA)	Claims	1-11 (yes)

2. Citations and explanations

see separate sheet

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/GB03/03393

Re Item III**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Since claim 12 is directed to a method of treatment of the human or animal body by surgery, it relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. For the assessment of the subject-matter of present claim 12 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. Therefore, no opinion will be formulated with respect to the subject-matter of claim 12 (Article 34(4)(a)(i) PCT).

Re Item V**Reasoned statement under Rule 66.2(a)(ii) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document (D1) cited in the International search report:

D1 ... US 5,108,413 A (Moyers R.E.)

Document D1 discloses (cf. claims 1, 2, 10, 11) a dilator for opening the lumen of a tubular organ comprising an elongated flexible expansion member of a material having a negative Poisson ratio. This disclosure is novelty-destroying for the subject-matter of claim 1 of the present application according to Article 33(2) PCT.

Document D1, which is considered the most relevant state of the art, discloses (cf. col. 1, lines 43-45 ; claims 1, 2, 10, 11) a dilator for opening the lumen of a tubular body organ comprising an elongated flexible expansion member of a material having a negative Poisson ratio to obtain a known and controllable radial expansion.

Thus, D1 not only addresses the same technical problem as the present application, i.e. to obtain a known and controllable radial expansion, but also provides the same solution, i.e. a tubular liner comprising an auxetic material.

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/GB03/03393

Furthermore, the subject-matter of claims 1-11 of the present application is not limited to implants or biocompatible liners, so that the technical problem is not solved over the whole scope of the claims.

Therefore, the subject-matter of claims 1-11 is not considered to involve an inventive activity according to Article 33(3) PCT.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☒ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.